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## **“It’s about actually having a proactive regulatory framework versus a reactive one”—Stakeholder Perspectives on the Governance of Embryonic Stem Cell Research in Ireland**

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### **Abstract**

Over the past 20 years, the ethical concerns associated with embryonic stem cell research (ESCR) have been the source of great debate. Due to the promise of ESCR, many jurisdictions have introduced regulations to govern it. Despite this, Irish policymakers have failed to introduce legislation to regulate ESCR and embryo research. Successive calls for legislation were ignored until the publication of the General Scheme of the Assisted Human Reproduction Bill 2017 in October 2017. Although the publication of the Heads of this Bill is welcomed, there have been no attempts to assess the current regulatory framework and its impact on the development of stem cell research in Ireland. To address this vacuum, empirical research was conducted with scientists, regulators and funders to explore the current regulatory framework in Ireland. This paper reports on and discusses the findings of these interviews and critically reviews the 2017 Bill.

### **Introduction**

Since the announcement of the creation of the first embryonic stem cell line in 1998, embryonic stem cell research (ESCR) has been the source of considerable debate worldwide. To grapple with these legal and ethical issues, numerous bioethics councils and individual governments have commissioned reports to consider the scientific, legal and ethical issues, and various legislative schemes have been introduced to oversee the research. Although the status of the embryo will be an ever-present topic, it is no longer the only concern in the regulation of ESCR. The conversation has now moved to the risk-benefit ratio and distributive justice,<sup>1</sup> and conversations have begun to focus on the ethical and legal implications of human embryo genome editing.<sup>2</sup> Despite this progress in science, Irish policymakers have failed to introduce legislation to regulate ESCR and embryo research. Successive calls for legislation were ignored until the publication of the General Scheme of the Assisted Human Reproduction Bill 2017 (the “GSAHR Bill 2017”) in October 2017.

Attempts to bring legislative clarity are welcomed, but there has been no attempt to assess the current regulatory framework and its impact on the development of stem cell research in Ireland. This paper seeks to address this vacuum. It will provide a brief overview of the status of the embryo and ESCR in Ireland and provide a basis for this study. Key findings of the interviews will be presented and discussed in light of the GSAHR Bill 2017. It will conclude with some commentary on the GSAHR Bill 2017 and recommendations for change before it becomes law.

### **Status of Embryonic Stem Cell Research in Ireland**

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<sup>1</sup> G. Cossu et al., “Lancet Commission: Stem cells and regenerative medicine” (2018) 391(10123) *Lancet* 883–910.

<sup>2</sup> D. Pei et al., “Human Embryo Editing: Opportunities and Importance of Transnational Cooperation” (2017) 21(4) *Cell Stem Cell* 423–426.

Until May 2018, the “unborn” in Ireland was constitutionally protected by virtue of the Eighth Amendment to the Constitution—Art.40.3.3°. The purpose of the amendment was to constitutionally prohibit abortion, but it contained no reference to abortion. Rather, the Eighth Amendment introduced the undefined term “unborn” into the Constitution, resulting in much uncertainty as to its scope, including whether it encompassed the embryo *in vitro*. During parliamentary debates, little consideration was given to its possible implications on embryos *in vitro*. Such an omission was a considerable oversight considering the birth of Louise Brown—the first person born through *in vitro* fertilisation (IVF)—had occurred in 1978, and it was known that embryos could be developed outside of the womb. A proposed amendment by (the then) Senator Catherine McGuinness—a member of the opposition in the Seanad—to explicitly state that constitutional protection applies after implantation would have clarified that constitutional protection applied to embryos *in vivo* only, but this was rejected.<sup>3</sup>

Despite the Attorney General’s criticism of the wording of the amendment,<sup>4</sup> and the lack of legal advice sought prior to the publication of the amendment,<sup>5</sup> it was ultimately passed. The prediction that the amendment would open a “legal Pandora’s Box”<sup>6</sup> came to fruition, and in the following decades, the courts have been occupied with abortion and circumstances in which it is constitutionally permissible to have an abortion in Ireland. The Protection of Life During Pregnancy Act 2013 came after a series of High Court, Supreme Court and European Court of Human Rights judgments in which there were successive calls for clarification within this context.<sup>7</sup>

The possible impact of Art.40.3.3° on embryos *in vitro* was largely ignored until the Constitution Review Group called for a definition to clarify, amongst other things, the impact of the Eighth Amendment on assisted reproductive technologies and, by implication, ESCR.<sup>8</sup> Aware of the growing need to regulate assisted reproductive technologies, the government appointed the Commission on Assisted Human Reproduction (CAHR) in 2000.<sup>9</sup> Its 2005 report, and a subsequent report by the Irish Council for Bioethics (ICB) in 2008, considered the legal status of the embryo.<sup>10</sup> Both groups were of the view that, although the matter would need clarification from the Supreme Court, the embryo *in vitro* is not protected under Art.40.3.3°.

Clarification came in *Roche v Roche*<sup>11</sup> when the High Court and Supreme Court were asked to consider whether the protection under Art.40.3.3° extended to embryos *in vitro*. Both courts recognised the difficulty in determining the status of the embryo, as it requires choosing one moral viewpoint over another in a debate that may have no common agreement. McGovern J. in the High Court noted that “[t]he fact that something is not prohibited by the law does not of itself mean that it is morally

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<sup>3</sup> Seanad Debates 1983, vol.100, col.1092.

<sup>4</sup> “Attorney General Rules Out Wording”, *The Irish Times* 16 February 1983, p.6.

<sup>5</sup> “Abortion Text Not Yet Available”, *The Irish Times*, 16 March 1983, p.5.

<sup>6</sup> Máire Geoghegan-Quinn TD, Dáil Debates 2 March 1983, vol.340, col.1622.

<sup>7</sup> *Attorney General v X* [1992] 1 I.R. 1; *A and B v Eastern Health Board* [1998] 1 I.R. 464; *A, B and C v Ireland* (2011) 53 E.H.R.R. 13.

<sup>8</sup> Constitution Review Group, *Report of the Constitution Review Group* (1996), p.275. The first ESC line was not derived until 1998 and thus did not form part of the analysis of the Constitution Review Group.

<sup>9</sup> Commission on Assisted Human Reproduction, *Report of the Commission on Assisted Human Reproduction* (2005).

<sup>10</sup> Irish Council for Bioethics, *Ethical, Legal and Scientific Issues Concerning Stem Cell Research* (2008).

<sup>11</sup> *Roche v Roche* [2010] 2 I.R. 321.

acceptable to carry out that act”, but the duty of the courts is to implement and apply the law, not morality.<sup>12</sup>

In holding that the embryo *in vitro* is not protected under Art.40.3.3°, <sup>13</sup> the courts did note that the embryo is deserving of respect. The extent of this respect and the protections that society may afford to it is not something for the courts to decide, but attention was drawn to the impact that holding that the embryo *in vitro* is the “unborn” may have on widely-used contraceptive practices that permit fertilisation but prevent implantation.<sup>14</sup> The courts stressed the need to introduce legislation as the science will continue to advance.<sup>15</sup> Geoghegan J. considered that a continued failure to protect in law the embryo “is undesirable and arguably contrary to the spirit of the Constitution”, and the Supreme Court noted that should the matter come before the courts again, it would be forced to consider the legal status of the embryo.<sup>16</sup>

Around this time, University College Cork (UCC) and Trinity College Dublin (TCD) published guidelines permitting the use of embryonic stem cells (ESCs), and based their guidelines on the recommendations of the ICB report.<sup>17</sup> However, accessing funding has proved to be problematic, as the biggest funders of science in Ireland—Science Foundation Ireland (SFI) and the Health Research Board (HRB)—have been instructed by the Department of Health since 2009 not to fund ESCR until legislation on assisted reproduction and associated research is introduced.<sup>18</sup> Despite clarification from the Supreme Court that there is no constitutional impediment to ESCR in Ireland, this moratorium remains in place. In October 2017, the GSAHR Bill was published and it is the first legislative initiative to regulate ESCR in Ireland. However, despite the proposed changes, there have been no attempts to date to engage with researchers on this matter.

This study seeks to address this vacuum and it is the first study to explore the impact of the current policy on scientific research in Ireland. Since these interviews were conducted, the GSAHR Bill 2017 was published and thus the findings of this study will inform a discussion on the Bill.

## Methodology

This was a qualitative research project involving face-to-face in-depth interviews with 16 key stakeholders. Using purposive sampling, respondents were selected based on their expertise in stem cell research and the regulation of science in Ireland. Other respondents were identified through snow

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<sup>12</sup> [2010] 2 I.R. 321 at 340.

<sup>13</sup> For critiques of this decision, see W. Binchy, “Article 40.3.3 of the Constitution: Respecting the Dignity and Worth of Human Beings” in J. Schweppe (ed.), *The Unborn Child, Article 40.3.3° and Abortion in Ireland: twenty-five years of protection?* (Dublin: The Liffey Press, 2008), p.195.

<sup>14</sup> [2010] 2 I.R. 321 at 347–348.

<sup>15</sup> [2010] 2 I.R. 321 at 383.

<sup>16</sup> [2010] 2 I.R. 321 at 393.

<sup>17</sup> [2010] 2 I.R. 321 at 393.

<sup>18</sup> See Trinity College Dublin, *Policy on Good Research Practice* (2009) and University College Cork, *Code of Practice for Research Using Embryonic Stem Cell Lines* (2008), available at: <https://www.ucc.ie/en/news/archive/2014andbeyond/2008pressreleases/ucc-statement-following-governing-body-meeting-of-28102008-at-which-consideration-was-given-to-embryonic-stem-cell-research-recommendations.html> [accessed 19 November 2018].

<sup>19</sup> SFI Policy on Research Using Human Embryonic Stem Cells, available at: <http://www.sfi.ie/funding/sfi-policies-and-guidance/ethical-and-scientific-issues/> [accessed 9 October 2018].

balling sampling. Respondents included scientists, geneticists, embryologists, funders of scientific research, regulatory bodies and lawyers.

All respondents, with the exception of three, were based in Ireland. The remaining three comprised of one scientist who completed their undergraduate training in Ireland and is now based in the UK was interviewed to assess the impact that the current status of ESCR has on their career decisions and two lawyers based in the UK who were selected due to their experience working in the legal aspects of biotechnology and the life sciences internationally. Although the original intention was to focus on scientists, health care professionals and funders, it was deemed necessary to have in-depth discussions with lawyers on features of forthcoming legislation.

The interviews lasted approximately 50 minutes each and took place between April and June 2017. After outlining the project and the purpose for the interview, written informed consent for participation and recording of the interview was obtained. Interviews explored the status of science and funding for science in Ireland, the impact that the current framework has had in Ireland and interviewees' reflections on the regulation of ESCR.

All interviews were conducted in English, recorded and transcribed verbatim. Data analysis was facilitated by using the software Nvivo. A contextualised thematic approach was used to interpret the results. This study was approved by the Research Ethics Committees at Middlesex University.

## **Results**

The findings of this study paint a worrying picture for the regulation of stem cell research in Ireland. National scientific policy was heavily criticised by the scientists as being short-sighted. They confirmed that ESCR is not currently taking place in Ireland and that there is an inconsistency in the treatment of the differing cells and tissues used for research in Ireland. The findings revealed that the lack of regulations for ESCR has had a negative impact on research in Ireland, specifically induced pluripotent stem cell (iPSC) research, as well as an impact on the development of the careers of many of the respondents. All respondents called for clarity and transparency in this area in the form of legislation as well as the re-establishment of an independent national bioethics framework.

### ***Status of ESCR in Ireland***

It is clear from these interviews that no ESCR is currently ongoing in Ireland. Respondents confirmed that there is no public funding available for ESCR in Ireland and this includes European funding (such as Horizon 2020 or European Research Council funding), as this falls under exchequer funding. The Irish funding bodies have collaborations with international bodies such as the National Institutes of Health (NIH) in the US and the Wellcome Trust in the UK, and the Memorandum of Understanding between these bodies excludes ESCR from the funding remit. Funders made it clear that these prohibitions will remain in place until such time as legislation permitting ESCR is introduced.

Pertaining to the private funding of ESCR, it was felt that the lack of medical charities investing in research and development in Ireland, compared to the rest of the world, hampered access to other forms of funding. Respondents who did want to pursue ESCR felt that they were unlikely to get other forms of external funding while the legal uncertainties remain.

*We can be part of European projects, where other partners in their own countries, where the legislation is different, can do embryonic stem cell work, we can't and our researchers can't. (03, Funder)*

*If you're going up against other European countries that have solid stem cell legislation, you're more likely to not get funded ... you can't have a national standard of stem cell research, you really have to have an international standard ... that would be having access to all the same cell types that other countries have under strict supervision. (02, Scientist)*

Many respondents were highly critical of the unwillingness of the government to engage in many difficult and complex scientific areas such as ESCR and assisted human reproduction (AHR), and there was consistent criticism amongst respondents of the (at that time) ongoing failure to provide a legislative solution. Attention was drawn to bodies such as the Health Products Regulatory Authority (HRPA), but this body manages the service and quality management system of AHR and associated research; thus, oversight of the difficult ethical questions pertaining to AHR remain.

### ***Incoherence, Inconsistency and Academic Freedom***

Throughout the interviews, respondents were critical of the current funding framework for science and ESCR policy in Ireland. In particular, there were four criticisms and concerns.

First, amongst the scientists there was widespread criticism of the current funding policy for science generally. Although funders noted that their budgets had not decreased after the economic downturn, the focus has shifted away from the funding of fundamental science. The focus of the main funding bodies in Ireland is applied research—a move respondents felt has been driven by the Government and supported by industry, with the aim of job creation. Although it was noted that this is a trend across the world, in Ireland there is a real lack of funding for fundamental research. Respondents felt that this is problematic, as fundamental research feeds applied research; thus, the funding of fundamental science is necessary to fuel the research cycle. Without this, Ireland is failing to build a self-sustaining system for research. Many also felt that this policy has led to difficulty in attracting and retaining good researchers. Almost all scientists reflected that they would not have achieved their successes in the current funding environment, and likely would not remain in Ireland if they were an early career researcher.

*Our budget did not decrease with the economic downturn, which was obviously very favourable. (02, Funder)*

*They don't realise that many of the best discoveries in medicine and science come about by simply very good scientists just having inquisitive minds. (01, Scientist)*

Secondly, the inconsistencies in policies pertaining to different cells were criticised. It was noted that research using both foetal cells and human embryonic kidney (HEK) cells is currently ongoing and publicly funded in Ireland. Foetal cells are generally acquired abroad and can come from an aborted foetus or a miscarriage, while a HEK cell is an immortalised cell line that originated from a HEK. Respondents felt that a policy that funds HEK cell and foetal cells research but prohibits the funding of ESCR is illogical, but likely due in part to a lack of understanding of the different types within the Department of Health.

*This is a cell that's derived from a human embryonic kidney cell ... it is from a human embryo and yet people would be very concerned about using human embryonic stem cells, but not human cells that come from an embryonic kidney and these cells are being used and there's no impediment to use them. (05, Scientist)*

*It has to be said that every virology lab in the State uses embryonic cells and they have the same considerations that embryonic stem cells have, but we can use them willy-nilly, without any regulation. (07, Scientist)*

Thirdly, in discussing the ban on ESCR, some felt that this policy had a negative effect on iPSC research in Ireland. It was clear from discussions that Ireland is active both in adult stem cell research and iPSC research. One respondent reflected that perhaps the development of iPSC research has done away with the need to consider the ethics of ESCR in Ireland. For the remainder of respondents, it was a scientific issue; discussions focused on the inability to use ESCs as a control and whether this was a dis-service to Irish researchers. Those currently using iPSCs did not feel that they were disadvantaged and the funders noted that all applications went through international peer review and were approved to be of the highest standards. However, the majority of researchers did feel that, for research using iPSCs, an ESC control is necessary.

*I mean and that is our concern generally about this area, that we think, that these are workarounds. But they're not ideal workarounds and it would be much better if you could have the whole suite ... it's just that there's not a whole pile we can do about it at the moment ... unfortunately our hands are tied in this and I mean, the researchers themselves have concerns about this as well, but until somebody has the balls to actually take this legislation and sort it out, we really are hamstrung, which is a shame. (03, Funder)*

*Of course you need to use an embryonic control ... otherwise you're not comparing like with like, you have no idea. (06, Scientist)*

Finally, in discussing funding generally, the funders made it clear that outside of targeted calls for a specific area of research, they do not dictate to researchers what research to do. However, for those who did wish to use ESCs, it was clear that the lack of funding had impacted their decisions on their own career paths. They felt that this had negatively impacted them as “there’s a clear piece missing”. The funders did highlight that even if there was no moratorium from the Department of Health on the funding of ESCR, it could still fall under the internal rule that has seen a move away from the funding of fundamental to applied research.

*I was just put off by the fact that there's a sort of grey ... I'd never have got it through the internal ethics processes because there was no external framework for them to work to. (03, Scientist)*

Throughout the discussions with the scientists, it was clear that they had to restructure their research due to the funding rules surrounding fundamental research and ESCR. For those who had wished to pursue ESCR, this was felt more starkly. The funders did acknowledge that it is possible to secure funding for fundamental research either through international funding bodies, one of the co-funded schemes with international partners, or “sneak in a bit of fundamental into their applied project”. However, it is not currently possible to access funding for ESCR. One respondent felt that the current

funding ban impinges on his right to academic freedom under the Universities Act 1997. Even if private funding could be sourced, some respondents felt that Irish universities are risk averse and likely to be too concerned with the exposure and potential political implications of such research to permit it to proceed.

*Funding agencies can decide what they want to fund ... that's true up to a point ... but to get down to individual cell lines and say, you can use this cell line but you can't use that one, that's something that has never done and that's political interference, pure and simple. (08, Scientist)*

*They may want to do it but their institutions may be deterred from allowing them to do it because of the concerns about what might happen and the political ramifications. (01, Clinical geneticist)*

### **Clarity and Transparency**

The need for clear and transparent structures for ESCR and science generally was a consistent theme throughout all interviews and can largely be grouped into: clarity and transparency through legislation; a regulatory framework; and a national bioethics council.

#### **(1) Legislation**

In reflecting upon possible legislation, all respondents stressed the need for clarity and transparency. Clarity was necessary regarding the boundaries of permitted research, but also regarding the permissibility of future therapies arising from ESCR. It was felt that this is necessary for public confidence in the system. Many respondents noted the importance of ensuring that any legislation be harmonised with the European standard, and that a national standard of stem cell research should be avoided in favour of an international standard to improve chances of international funding success.

*So, I think that, you know, on a number of fronts, in terms of like scientific integrity, in terms of value for money for taxpayers' investment and in terms of soliciting more international investment, you need to have transparency and transparency is given through regulation. (02, Scientist)*

*I think it would need to be consistent with what is deemed best practice in other European countries. (03, Scientist)*

Respondents felt that critical issues, such as the status of the embryo, what can be done with an embryo, source of ESCs, and the permitted purpose of research must be clarified. When probed on this matter, respondents found it difficult to select a cut-off point for research on the embryo. Different biological markers, such as the appearance of the neural tube and differing cut-off points such as day 10, 14 or 18 were noted as possibilities. They also had difficulty in defining an embryo, feeling that both matters should be left to the "lawyers".

*I think issues around consent in terms of, as I say and it always seems to boil down to the generation of the cell lines, so I think that it would be very important to see strong issues around consent ... I think there would have to be very clear guidelines within the legislation about the circumstances under which eggs could be harvested, or under which embryos could be used, you know and that they would have, so I think it would be more around the guidelines*



*and the criteria as to what would actually qualify under the legislation as an embryonic stem cell line that could be used for research. (01, Funder)*

*Try to define an embryo, good luck is all I can say, because there's, you know, I think people will have trouble defining exactly what an embryo is, because conception or fertilisation is a definite time point, but after that, everything is gradual. So you'll have to say, okay, look, you can do research on cells derived from an embryo up to this time point, but I think you might get arguments as to what that time point is. (05, Scientist)*

Looking to the future, respondents felt that legislation should also address possible future therapies to ensure that they are permitted in Ireland. Such legislation should allow for the testing of certain diseases and the provision of therapies. It was noted that even if treatments become available from ESCR, Irish policymakers would undoubtedly make these treatments available to patients in Ireland. The inconsistency of permitting access to therapies while also prohibiting ESCR was highlighted.

*If there was a treatment for, say, Alzheimer's Disease, developed tomorrow in the US using human embryonic stem cells, at some stage I would see that treatment coming into Ireland. So it's an Irish solution to an Irish problem, where we don't allow the research ourselves but we're quite happy to benefit from it if it's done somewhere else. (Voice 11)*

## (2) Independent regulatory body

Respondents considered that some independent body should oversee this research and it should not be left to individual institutions. The UK Human Fertilisation and Embryology Authority (HFEA) was frequently favourably mentioned as a body that worked well and provided confidence to the public by demonstrating that the research is well controlled. The HPRA was also mentioned as a body that functions well with clear regulatory oversight.

*I think it probably deserves a separate body like HFEA because it gets quite complex. (01, Regulator)*

*I think it needs to be national, I think it's such a big question. I don't think it's right or fair or appropriate that the universities deal with it on an institutional level. I think it has to be considered at a national level. (04, Scientist)*

Such a body could also be tasked to respond to future technological and scientific change, both in the area of stem cell research and other emerging technologies that require legal, ethical and scientific reflection, such as gene editing and CRISPR technology. As such, the importance of staffing this body with experts who can address the complex and interdisciplinary issues was stressed.

*It's about actually having a proactive regulatory framework versus a reactive one. (02, Scientist)*

## (3) National Bioethics Council

During Ireland's economic downturn, the ICB was disbanded as a purported cost-saving measure. Although the National Advisory Committee on Bioethics (NACB) was established within the Department of Health in 2012, the closing of the ICB was lamented by many respondents. Although this body has been reconstituted into an advisory body for the Department of Health, it was felt that

this was a real loss to science in Ireland. It was felt that the NACB lacks independence as, unlike the ICB, the Minister for Health is now in charge of setting the agenda. This was perceived to be problematic.

The role that the former Council had in engaging the public on bioethical issues was also noted and the reconstituted group no longer has that function. Respondents felt that the ICB had an important role in engaging scientists and bioethicists with the public and the closure has left a void. It was also felt that the ICB had an important role in demonstrating that bioethics has an important role in the governance of science to outside investors.

*In reconstituting something as an advisory group for bioethics for the Department of Health it meant the Department of Health sets the agenda. It isn't that this group could meet and decide what are the things they want to do ... can't choose its own agenda and set its own reports. It's responding to the Minister, rather than setting up its own independent agenda. (01, Clinical geneticist)*

*We had seen a gradual development of science regulatory structures ... we had seen things like the establishment of the Bioethics Council. (02, Scientist)*

### **Reproductive Health and Embryonic Stem Cell Research**

Respondents were unanimous that abortion is not linked with the regulation of ESCR, but some felt that the (then) forthcoming abortion referendum could have an impact on the ESCR debate. The abortion debate could make politicians reluctant to introduce legislation on embryo research but, on the other hand, some felt that the liberalisation of the laws on abortion could help the passage of ESCR regulations. Whatever the impact, some respondents felt that the abortion issue should be resolved prior to the introduction of policy on ESCR.

When asked whether AHR and ESCR should be regulated at the same time, respondents were divided. Some felt that although the ethical issues in ESCR and AHR are aligned, as both are dealing with an embryo, the purpose of both technologies is different. The purpose of AHR is a successful pregnancy while ESCR is focused on research, therefore the ethical considerations are different.

*I think they're utterly different sectors. Just because they happen to involve at some level the same type of cell to start with, on the one hand you're talking about allowing people to have children and on the other hand, you're talking about scientific use of stem cells. I can't see any link between the two, I think they're quite different. (04, Scientist)*

Respondents who thought that ESCR and AHR should be regulated together based their beliefs on two separate considerations. First, in juxtaposition with the previous group, they felt that as both are concerned with an embryo, they are inextricably linked. AHR will create many supernumerary embryos and a decision must be made as to the use of these embryos. Respondents felt that the use of these embryos for research should be a part of this conversation.

Secondly, some respondents felt that AHR is closely linked with research, and in particular embryo research. The historical link between fundamental research and AHR was highlighted and one respondent noted that IVF came about from research on embryos. Some respondents also noted that we know very little about early embryo development and in fact have a better understanding of the

first month of embryo development in mice than in humans. Research on this early embryonic stage is important in better understanding the causes of miscarriage and the development of serious diseases *in utero*. Thus, it is important that we do research on embryos up to, and potentially past, 14-day-old embryos.

*I don't think you can separate them, because at the end of the day, you're creating life outside of the human body and something has to happen with the resulting embryo that doesn't get implanted.* (07, Scientist)

*You could say they're separate things, but assisted reproduction should be relying on talking to [fundamental] research.* (08, Scientist)

## Discussion

Since these interviews were carried out, the GSAHR Bill 2017 has been published. The Bill seeks to provide for: the regulation of AHR; gamete and embryo donation for use in AHR treatment and research; posthumous assisted reproduction involving the gametes or embryos of a deceased person under certain conditions; pre-implantation genetic diagnosis and sex selection; surrogacy; embryo and stem cell research; and the establishment of an independent regulatory authority for AHR.

ESCR, AHR and associated therapies are intended to be regulated under the same legislative scheme. Such an approach makes pragmatic sense, but the sheer breadth of issues to consider does raise concerns that all issues will not be sufficiently considered. The proposed regulatory framework for ESCR has been subject to some academic criticism,<sup>19</sup> but since the publication of the GSAHR Bill 2017, surrogacy is the issue that has attracted most attention.<sup>20</sup>

There have been considerable developments in the realm of embryo research, most notably mitochondrial replacement techniques and embryo editing since the publication of the CAHR report that have not been discussed in Ireland. The 14-day rule has also become the subject of debate in light of scientific developments that now make it possible to culture an embryo beyond this date. The germline modification of embryos raises considerable ethical considerations that perhaps should be considered, prior to the introduction of any legislation in this area. In the UK, there has been considerable scientific, legal and academic discussion as well as public debate on these matters—conversations that have not taken place in Ireland. Although discussions at the committee stage have yet to commence, it is essential that each of these issues receive sufficient discussion and debate.

## ***Governance of Cells and Tissues in Ireland: An Ongoing Inconsistency***

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<sup>19</sup> C. Staunton, “The regulation of stem cell research in Ireland: From the Commission on Assisted Human Reproduction to the Assisted Human Reproduction Bill 2017” (2018) 18(1) *Medical Law International* 35–58.

<sup>20</sup> B. Tobin, “Surrogacy proposals would make process costly, time consuming and frustrating”, *TheJournal.ie*, 27 October 2017, available at: <http://www.thejournal.ie/readme/opinion-surrogacy-proposals-would-make-process-costly-time-consuming-and-frustrating-3666377-Oct2017/> [accessed 9 October 2018]; D. Quinn, “Three’s a crowd when it comes to mothers”, *The Times*, 22 October 2017, available at: <https://www.thetimes.co.uk/article/threes-a-crowd-when-it-comes-to-mothers-kdcn5l0vx> [accessed 9 October 2018].

Prior to the publication of the GSAHR Bill 2017, there was a real moral inconsistency in the treatment of embryos. In the intervening years since the court in *Roche* held that the embryo *in vitro* has no protection in law, successive governments failed to introduce legislation on this matter. It left Ireland in the situation whereby there is absolute protection for the embryo *in vivo* and no protection in law for the embryo *in vitro*. The GSAHR Bill 2017 does remedy this inconsistency and provides some protection for the embryo *in vitro*, but the strict rules on the use of pluripotent stem cells, irrespective of the source of these cells, introduces a new and unwarranted inconsistency.

Foetal cells and HEK cells will continue to be used in Irish laboratories, but not under the strict conditions laid down by this Bill. Head 63(2) puts the same restrictions and conditions on iPSCs as ESCs. iPSCs are reprogrammed adult stem cells that are pluripotent and have many similar characteristics as ESCs.<sup>21</sup> These cells do not involve the destruction of an embryo and, as such, do not attract the same ethical controversy. The use of these cells has the same ethical consideration as the use of any other somatic cell, and attracts less ethical controversy than a foetal or HEK cell. However, the justification in the explanatory note for treating iPSCs and ESCs the same is, “while their source (i.e. adult somatic cells) is not controversial, the potential uses to which they can be put are similar to ESCs”. The source of ESCs is controversial, but the potential use of these cells is not. It is thus unclear why iPSCs whose source and use are relatively free from controversy, will be subject to strict regulatory scrutiny simply because the use of iPSCs and ESCs are the same. If the policy is to regulate cells based on their potential uses rather than their source, other cell types must be included in this regulatory framework. Adult stem cells and tissue cells such as chondrocytes or keratinocytes may also be put to the same use,<sup>22</sup> and the justification for distinguishing adult stem cells and iPSCs is unclear. The inconsistency of this proposed policy change is further highlighted when one considers that HEK cells and foetal cells will not be subject to these strict requirements.

This policy is also out of step with international best practice in this area. In the most recent revision of the International Society for Stem Cell Research (ISSCR) Guidelines, it is explicitly stated that as iPSCs do not encounter the same ethical sensitivities as ESCs, iPSC research does not require specialised review.<sup>23</sup> The additional regulatory burden on iPSCs is unnecessary and likely to discourage scientists in Ireland from using such cells.

### ***Governance of Science in Ireland***

In its report on stem cells and regenerative medicine, the Lancet Commission speaks about the importance of the social contract with the public in the field of regenerative medicine. It raises the concern that poor-quality science, funding models that lack clarity, unrealistic expectations and rogue clinics offering false cures are threatening the social licence to conduct such research.<sup>24</sup> The Lancet Commission recommends that the challenges facing regenerative medicine and stem cell research can be resolved by a strategy that involves better science, better funding models, better governance and

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<sup>21</sup> J. Yee, “Turning Somatic Cells into Pluripotent Stem Cells” (2010) 3(9) *Nature Education* 25 at 25.

<sup>22</sup> The author expresses gratitude to Prof. Frank Barry for a discussion on this point.

<sup>23</sup> International Association for Stem Cell Research, *Guidelines for Stem Cell Research and Clinical Translation* (2016), para.2.1.

<sup>24</sup> G. Cossu et al., “Lancet Commission: Stem cells and regenerative medicine” (2018) 391(10123) *Lancet* 883–910.

better public and patient engagement.<sup>25</sup> The findings of this research point to problems in the governance of science generally, and in particular the regulation of ESCR in Ireland. It is clear that the lack of legal clarity, and the de facto ban on ESCR due to the prohibition of funding for it, has an impact on the governance of science, the quality of science in Ireland and the attractiveness of Ireland as a research environment. In considering the findings of this study, one cannot but feel that the social licence to conduct ESCR in Ireland, while not completely broken, is in danger of breaking, largely due to poor governance of science generally and government inaction on ESCR.

For Ireland, it is clear from this study that the governance of science is problematic. While heartening that the importance of bioethical governance for research was stressed by so many respondents, at the heart of the governance problem is the lack of an independent bioethics infrastructure. It is both a symptom and a cause of the governance issues: the lack of an independent body deprives us of an opportunity to publicly engage in many of the major bioethical issues raised by developments in new technologies, but it also speaks volumes about the continued reluctance of Irish policymakers to address such issues.

Article 19 of the UNESCO Declaration on Human Rights and Bioethics talks about the importance of an “independent, multidisciplinary and pluralist ethics committee”, both at a local and national level. At a local hospital or university level, such committees are required to provide clinical guidance (presumably in the form of a clinical ethics committee) and to provide an ethical, legal, social and scientific assessment of research (presumably in the form of a research ethics committee). Article 19 also speaks to the importance of assessing “scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines”, and fostering “debate, education and public awareness of, and engagement in, bioethics”. A national bioethics committee thus has a role in the development of guidelines, but also in fostering public education and debate.

The importance of an independent committee is that it will have the necessary expertise and time to engage with the issues associated with developments in biotechnology, and can attempt to balance the interests of human rights, science and public policy in an environment that should be free from political influence.<sup>26</sup> However, the task of the Irish National Advisory Committee on Bioethics seems to be restricted to supporting the work of the Minister for Health and the Department of Health. Its normative function is weak and its role in public engagement non-existent. A body that develops opinions in response to a ministerial request can only have a limited role in developing national guidelines or stimulating public debate.

The CAHR and ICB reports are also outdated; the CAHR report did not consider IPSCs and neither report considered mitochondrial replacement transfer or gene editing. Independent bioethics councils across the globe are developing opinions and policies in these areas, yet Ireland continues to shy away from these major bioethical discussions. For a social licence to operate, there must be some public understanding of these issues, but the infrastructure in which such a discussion can take place in Ireland is lacking.

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<sup>25</sup> G. Cossu et al., “Lancet Commission: Stem cells and regenerative medicine” (2018) 391(10123) *Lancet* 883–910.

<sup>26</sup> E. Petit, “An Ethics Committee for Patent Offices?” in A. Plomer and P. Torremans, (eds), *Embryonic Stem Cell Patents: European Patent Law and Ethics* (Oxford: Oxford University Press, 2010), p.309.

The developing discussion on the GSAHR Bill 2017 is likely to attract controversy that could at times be mired in misconceptions and untruths. An independent body can provide sound legal, ethical and scientific advice, free from the polarising rhetoric that is too often a feature of these debates. This is necessary for public debate, but also importantly for the legislature. While the Human Fertilisation and Embryology Act 1990 parliamentary debates were ongoing in the UK, the Voluntary Licensing Authority (VLA)<sup>27</sup> was established to issue licences and provide a minimum set of standards that clinics should follow in the interim. The VLA also took it upon itself to educate Members of Parliament about the science behind IVF. This was in response to a concern that the parliamentarians would be influenced by media reports that depicted IVF as growing foetuses in test tubes.<sup>28</sup> Furthermore, without an independent body that seeks to consider the legal, ethical and social issues with new technologies, Ireland will continue to have a reactive rather than a proactive regulatory regime.

## **Conclusion**

The development of stem cell legislation has been long-awaited. Currently, national agencies will not fund the research and the lack of legislation and national ethical oversight means other international agencies will not fund. The GSAHR Bill 2017 provides some clarity, but problems nevertheless remain. There is a continued inconsistency in the treatment of cells in Ireland, and the proposed legislation will bring unnecessary regulation to the use of iPSCs—cells that are generally perceived to be ethically uncontroversial. Wider governance issues also remain and the establishment of an independent bioethics council, with an engagement function, is necessary in Ireland. It is clear that before the GSAHR Bill 2017 becomes law in Ireland, Irish policymakers must consider the wider ethical and economic governance problems associated with science in Ireland.

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<sup>27</sup> This was later renamed the Interim Licensing Authority until it was named the Human Fertilisation and Embryology Authority under the 1990 Act.

<sup>28</sup> J Gunning & V English, *Human IVF: A Case Study on the Regulation of Medical Innovation* (Dartmouth 1993) 57.